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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,941	04/16/2007	Hiroshi Kawashima	47635-0024-00-US (226682)	7395

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EXAMINER	
SHOMER, ISAAC	

ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,941	KAWASHIMA ET AL.	
	Examiner	Art Unit	
	ISAAC SHOMER	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *6,7,24 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 8-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2 June 2006, 11 October 2006, 3 January 2007.

DETAILED ACTION

Election/Restrictions - Groups

Applicant's election with traverse of Group I, claims 1-23 in the reply filed on 6 October 2009 is acknowledged. The traversal is on the ground(s) that unity of invention is considered only in relation to independent claims, according to paragraph 10.06 of the PCT guidelines, and that the claims of Group II depend upon the claims of Group I. Applicant also asserts that the examiner must state grounds for unpatentability over 35 U.S.C. 102 or 103 to break unity in accord with MPEP 1893.03(d). This is not found persuasive because, according to PCT guideline 10.08, if an independent claim does not avoid the prior art, then the question is whether there is still an inventive link between all the claims dependent upon that claim a posteriori. The restriction requirement is proper because the claims do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same special technical feature, as demonstrated by Haynes. Furthermore, there is no requirement in MPEP 1893.03(d) that the examiner must state grounds of rejection over 35 U.S.C. 102 or 103 to break unity.

The requirement is still deemed proper and is therefore made FINAL.

Claims 24-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6 October 2009.

Election/Restrictions - Species

Applicant's election with traverse of phosphatidylserine as the phospholipid, and eicosatetraenoic acid in the reply filed on 6 October 2009 is acknowledged. The traversal is on the ground(s) that the examiner has mischaracterized the species election and has therefore made the election for the applicant. Applicant has elected the LCPUFA compound eicosatetraenoic acid, and has pointed out that arachidonic acid is a type of eicosatetraenoic acid. This is not found persuasive because the examiner did not make the species election for applicant, in that examiner allowed applicant to pick one LCPUFA species from those of instant claims 15 and 17.

The examiner further expands the election of the LCPUFA species to further include docosahexaenoic acid (DHA), as of claim 17.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6 and 7 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected specie of the phospholipid, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6 October 2009.

Claim Rejections - 35 USC § 112 1st Paragraph: Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, and 8-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See, e.g., In re Wilder, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did 'little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.')

Mere indistinct terms (such as "LCPUFA supply compound" used herein in claim 1), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice…. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See Univ. of Calf. V. Eli Lilly, 43 USPQ 2d 1398, 1406

(Fed. Cir. 1997). This is analogous to enablement of a genus under Section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. *If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus*. See MPEP 2163. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any *combination of such identifying characteristics that distinguish the claimed invention from other materials* and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here, the specification does not provide a reasonably representative disclosure of useful LCPUFA supply compounds generally, a potentially huge genus inclusive of many different compounds having widely divergent structures and functions. Specifically, the specification discloses only a limited number of species at page 10 last paragraph and onto the top of page 11 and these are not viewed as being reasonably representative of the genus in its claimed scope because no readily apparent combination of identifying characteristics is provided, other than the disclosure of those specific species as examples of the claimed genus.

Claims 14-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Mere indistinct terms (such as "sugar derivative ester" used herein in claim 14), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886 (CAFC 2004) at 1892, Univ. of Calf. V. Eli Lilly, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997), and MPEP 2163 as shown above.

Here, the specification does not provide a reasonably representative disclosure of sugar derivative esters generally, a potentially huge genus inclusive of many different compounds having widely divergent structures and functions. Specifically, the specification discloses only a limited number of species at page 15 first full paragraph, and these are not viewed as being reasonably representative of the genus in its claimed scope because no readily apparent combination of identifying characteristics is provided, other than the disclosure of those specific species as examples of the claimed genus.

Claim Rejections - 35 USC § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, 5, and 8-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “wherein respective proportions of the first component and second component are determined according to the number of hydrolysable fatty acid bonds contained in the original phospholipid molecules" of claim 1 is indefinite. This is because it is unclear what is being compared. The claim does not state the item to which the hydrolysable fatty acid bonds are being compared. Furthermore, one of ordinary skill in the art would not have known how to determine the appropriate proportion of the first and second component based on the number of hydrolysable fatty acid bonds in the phospholipid molecules. For the purposes of substantive examination under the art, this phrase will be interpreted as "wherein there is a proportion of first component and second component."

Claims 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This is because claim 14 defines the LCPUFA supply compound to include, among other possibilities, a fatty acid. It is unclear how the supply compound contains a fatty acid (which necessarily is a carboxylic acid), yet also will be hydrolyzed to form a fatty acid, which implies that the fatty acid carboxylic acid is not actually a carboxylic acid in the supply compound, but is something else (such as a fatty acid ester).

Claims 2, 3 and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Where values can vary depending on the basis for their determination, the claimed subject matter may be indefinite. *See* Honeywell Intl. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that, where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the value is indefinite when the claim fails to concurrently recite the method of measurement used to obtain it). Accordingly, the percent values recited by instant claims 2, 3 and 18-20 are incomplete insofar as they do not specify the frame of reference used to measure them, e.g., the proportion of LCPUFA. It is unclear whether the proportion of LCPUFA refers to the oil as a whole, or the first component (wherein said first component can be a fatty acid ester, and the ester portion, once hydrolyzed, is not a LCPUFA and thus the amount of LCPUFA in the first component, once hydrolyzed, is not necessarily 100%.

Claims 2, 3, and 17-20 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2, 18, 19, and 20 recite the limitation "suppliable fatty acids" in the claims upon which they depend. Claims 3 and 17 recite the limitation "suppliable LCPUFA" in the claims upon which they depend. There is insufficient antecedent basis for these limitation in the claim. As such, the terms “suppliable fatty acids” and “suppliable LCPUFA” are not defined.

Claims 14-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 describes a sugar derivative. This term is indefinite. The term “derivative” is indefinite because it is unclear how far one can deviate from the parent compound without the “derivative” being so far removed therefrom as to be a completely different compound. See the related rejection in the “Written description” section supra.

Claim Rejections - 35 USC § 102

For the purposes of substantive examination under the art, the phrase “wherein respective proportions of the first component and second component are determined according to the number of hydrolysable fatty acid bonds contained in the original phospholipid molecules" will be interpreted as "wherein there is a proportion of first component and second component." See supra rejection under 35 U.S.C. 112 2nd Paragraph.

For the purposes of examination, the definition of a “LCPUFA supply compound” is interpreted as including both a LCPUFA (e.g. a fatty acid such as arachidonic acid or a salt thereof) as well as a compound that is hydrolyzable to remove its LCPUFA (e.g. a glycerol ester). This determination is made in light of claim 14, which defines a LCPUFA supply compound to include a free fatty acid.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8-17, 19, 21, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by “Ultimate Ginkgo” (http://www.edietstar.com/fact_sheet/ultimate_ginkgo.pdf - 12 March 2003, as of Internet Archive) and based upon a public use or sale of the invention.

“Ultimate Ginkgo” describes a composition formulated as a tablet, wherein each tablet comprises 10 mg of docosahexaenoic acid (DHA) and 10 mg of phosphatidylserine derived from soybean, along with calcium, lecithin, and other compounds, as of page 1, right column of Ultimate Ginkgo. Hence, the weight ratio of DHA[1] and phosphatidylserine is 1:1. Based on the box labeled “Ordering Details” it is evident that said composition was for sale at the time the document entitled "Ultimate Ginkgo" was generated.

While Ultimate Ginkgo is silent as to the process by which the product was prepared, as of claims 8-13, there does not appear to be a structural difference between the composition of Ultimate Ginkgo and the instant claims. This is because patentability of a product (here the phosphatidylserine) does not depend on its method of production, and if the product in the product-by-process claim is the same as a product of the prior

[1] DHA is conjugated, as of page 11, first full paragraph of the specification.

art, the claim is unpatentable even though the prior product was made by a different process (derived from different materials). See MPEP 2113.

Claims 1-5 and 8-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Hiratsuka et al. (US 2003/0190392 A1).

Hiratsuka et al. (hereafter referred to as Hiratsuka) teaches, in "Embodiment 2" (starting paragraph 0054) a lipid mixture comprising 30.7% by weight neutrolipids[2] and 69.3% by weight phospholipids, wherein 9.5%-12.4% by weight of the phospholipids are phosphatidylserine, as of Hiratsuka, paragraphs 0056-0057. Phosphatidylethanolamine was also present, as of Hiratsuka, paragraph 0060. Hiratsuka further teaches that docosahexaenoic acid[3] comprises 50.2-55.2% by weight of the phosphatidylserine, and arachidonic acid comprises about 0.8-2.2% of the phosphatidylserine, as of Hiratsuka, paragraphs 0057-0058.

Phosphatidylethanolamine is a phospholipid, and the docosahexaenoic and arachidonic esters of phosphatidylserine are LCPUFA supply compounds.

While Hiratsuka is silent as to the process by which the product was prepared, as of claims 8-13, there does not appear to be a structural difference between the composition of Hiratsuka and the instant claims. This is because patentability of a product (here the phosphatidylserine) does not depend on its method of production, and if the product in the product-by-process claim is the same as a product of the prior art,

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[2] Triglycerides, as of Mong et al. (Journal of Pharmacology and Experimental Therapeutics), 1986, 239(1), page 65, top of left column.
[3] DHA is conjugated, as of page 11, first full paragraph of the specification.

the claim is unpatentable even though the prior product was made by a different process (derived from different materials). See MPEP 2113.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Ultimate Ginkgo" (http://www.edietstar.com/fact_sheet/ultimate_ginkgo.pdf - 12 March 2003, as of Internet Archive) as applied to claims 1-5, 8-17, 19, 21, and 23 above, and further in view of Stordy (US Patent 6,150,411) and Birch et al. (Developmental Medicine and Child Neurology, 2000, Vol. 42, pp. 174-181).

Ultimate Ginkgo teaches a combination comprising phosphatidylserine and DHA, as shown above.

Ultimate Ginkgo does not teach arachidonic acid.

Stordy teaches a solid composition comprising 100 mg of DHA and optionally 100 mg of AA[4], as of Stordy, column 3 lines 16-23, Example 1. Stordy further teaches an oil composition comprising 5% of DHA and optionally an equal percentage of AA, as of Stordy, column 3 lines 28-31, Example 3. Stordy suggests the incorporation of phospholipids, as of Stordy, column 2 lines 62-65. The composition for Stordy may be used for treatment of dyslexia or inadequate night vision, as of Stordy, column 2 lines 30-35.

It would have been prima facie obvious for one of ordinary skill in the art to have combined the arachidonic acid and phosphatidylserine combination of Stordy with the

[4] Arachidonic acid, as of Stordy, column 2 line 53.

phosphatidylserine and arachidonic acid combination of Ultimate Ginkgo. This is because the combination of Stordy is used for the treatment of dyslexia, and the composition of Ultimate Ginkgo is used for improvement of brain function. Furthermore, DHA supplementation might depress levels of arachidonic acid, as of Birch et al., page 175, right column, top of page, so one of ordinary skill in the art would have been motivated to have administered arachidonic acid to compensate for that change. Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ISAAC SHOMER whose telephone number is (571)270-7671. The examiner can normally be reached on 8:00 AM - 5:00 PM Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/I. S./
Examiner, Art Unit 1612

/JEFFREY S. LUNDGREN/
Primary Examiner, Art Unit 1639